

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

NO. 5:18-CV-220-FL

ANNIE MCNEIL-WILLIAMS,)	
)	
Plaintiff,)	
v.)	
)	
DEPUY ORTHOPAEDICS, INC.,)	PLAINTIFF'S SUPPLEMENTAL
DEPUY SYNTHES PRODUCTS,)	BRIEF IN RESPONSE TO
INC., JOHNSON & JOHNSON,)	MARCH 15, 2019 COURT ORDER
JOHNSON & JOHNSON SERVICES,)	
INC., JOHNSON & JOHNSON)	
CONSUMER COMPANIES, INC.,)	
SMITH & NEPHEW, INC., BIOMET)	
INC., ZIMMER BIOMET, INC.,)	
ZIMMER BIOMET HOLDINGS, INC.,)	
ZIMMER ORTHOPAEDIC)	
SURGICAL PRODUCTS, INC., and)	
DOE DEFENDANTS 1-100,)	
)	
Defendants.)	

I. The Fourth Circuit Court of Appeals Decision in *Burrell v. Bayer Corp.*

North Carolina district courts and the Fourth Circuit are not clear as to whether Plaintiff's failure to warn claim should be preempted in this case. Defendants rely solely on the district court decision in *Burrell v. Bayer Corp.*, 260 F. Supp. 3d 485. 496 (W.D.N.C. 2017) to support their claim that North Carolina has held that failure to warn claims predicated on failure to warn and manufacturing defect theories were preempted. *See Defendants'- Memorandum in Support of Their Motion for Summary Judgment*, pp. 18-19. However, the Judge in the recent Fourth Circuit Appeal decision in *Burrell* asserts that "the district court erred in its decision in denying the Burrells' motion to remand their case to state court *and deciding Bayer's motion to dismiss...The*

judgment of the district court is vacated.” Burrell v. Bayer Corp., 2019 U.S. App. LEXIS 7533,

*2. Here, in Defendants’ Supplemental Brief in Response to the Court’s Order, Defendants incorrectly assert that its reliance on the district court’s reasoning remains sound because the district court addressed the merits and the appeal did not. *See Defendants’ Supplemental Brief in Response to the Court’s Order*, p.2. However, while it is true that the *Burrell* Appeal was primarily decided based on jurisdiction grounds and not the merits of the motion to dismiss, the district court decision was nonetheless vacated, confirming that it cannot be relied on by Defendants in our case to warrant preemption.

Furthermore, while the Court of Appeals in *Burrell* has not come down one way or the other as to whether North Carolina law imposes a duty to report adverse events to the FDA—the Court of Appeals does confirm the *uncertainty* of state law on this specific duty, and suggests the possibility that North Carolina law does impose such a duty to report adverse events to the FDA. In Footnote 4 of the decision, the court’s decision supplements the hypothetical assumption that the ‘failure to report adverse events to the FDA’ is predicated on federal law, with the acknowledgement that in reality this is not a clear assumption that can be made; there is not clarity in many state laws as to whether defendants’ “Fraud on the FDA” claim is predicated on establishing violations of federal law and should be preempted. The court points to *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1232-33 (2013) (en banc), where the Ninth Circuit considered very similar state-law tort claims predicated on an alleged failure to report adverse events to the FDA, concluding that the plaintiffs’ claims were based on an independent state-law duty to warn that could be satisfied by reports to the FDA, running parallel to the defendant’s duties under federal law. *Burrell* was the only North Carolina district court decision to address this issue, and the decision is now vacated. This leaves open the question whether North Carolina’s duty to warn

includes adverse event reporting to third parties such as the FDA—a question that has not been made final by any North Carolina court. While Plaintiff concedes that other claims in Plaintiff’s complaint can be dismissed, Plaintiff’s negligence claims should not be for the reasons set forth in *Plaintiff’s Opposition to Defendant’s Motion for Summary Judgement*.

II. North Carolina Law’s Failure to Warn Duty Parallels the Federal Duty for Manufacturers to Warn

North Carolina law does impose a parallel duty to that of the federal duty for the manufacturer to warn and warranty. As discussed in *Plaintiff’s Memorandum in Opposition to Defendants’ Motion for Summary Judgment*, Under North Carolina law, the federal duties are parallel to North Carolina state law duty on manufacturers to warn and warranty. In North Carolina, the duty to warn extends beyond the time of sale and requires the manufacturer to make reasonable efforts to continue to convey an effective warning and warranties. In North Carolina, “a manufacturer of a product is under a duty to the ultimate purchaser, irrespective of contract, to use reasonable care in the manufacture and inspection of the article so as not to subject the purchaser to injury from a latent defect.” *Goodman v. Wenco Foods, Inc.* 333 N.C. 1, 26, 1992 N.C. LEXIS 671, *51, 423, S.E.2d 444 (1992). In North Carolina, A manufacturer must properly inform users of a product's hazards, uses, and misuses, or be liable for injuries resulting therefrom under some circumstances. *Smith v. Selco Products, Inc.*, 96 N.C. App. 151, 156 (1989), citing *Milikan v. Guilford Mills, Inc.*, 70 N.C. App. 705, 320 S.E.2d 909 (1984), *cert. denied*, 312 N.C. 798, 325 S.E.2d 631 (1985). If a product is inherently dangerous due to its design, then the manufacturer must provide an adequate warning that, at the very least, contains safety precautions that are “reasonably commensurate with the dangers involved.” *Smith v. Selco Products, Inc.*, 96 N.C. App. 151, 157 (1989), citing *Corprew v. Geigy Chemical Co.*, 271 N.C. 485, 157 S.E.2d 98

(1967). North Carolina also recognizes that a manufacturer has a continuing post-sale duty to warn consumers of dangerous defects that it later discovers. *Mills v. GMC*, No. 96-2359, 1997 U.S. App. LEXIS 18839, *6 (4th Cir. July 23, 1997), citing *Smith v. Selco Prods., Inc.*, 96 N.C. App. 151, 158, 385 S.E.2d 173, 176-77 (1989). *See also Sisk v. Abbott Labs.*, 1:11-cv-159 2012 U.S. Dist. LEXIS 112260, *15 (W.D.N.C. June 19, 2012).

A duty to warn arises when the supplier of a product knows or has reason to know that the product is, or can be, dangerous for the use for which it is supplied. *Smith v. Wyeth-Ayerst Labs. Co.*, 278 F. Supp. 2d 684, 706 (W.D.N.C. 2003), citing *Stegall v. Catawba Oil Co.*, 260 N.C. 459, 133 S.E.2d 138 (1963). A products liability plaintiff asserting a failure to warn claim must allege, and ultimately show, that the injury was caused by the defendant's failure to warn. N.C. Gen. Stat. § 99B-5; *Smith v. Wyeth-Ayerst Labs. Co.*, 278 F. Supp. 2d 684, 706 (W.D.N.C. 2003).

III. The Fourth Circuit on Whether Failure to Warn Duty Parallels the Federal Duty for Manufacturers to Warn

Decisions in other courts in the Fourth Circuit cited in *Plaintiff's Memorandum in Opposition to Defendant's Motion for Summary Judgment* support Plaintiff's position on North Carolina law. In *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733 *D. MD. Aug. 18, 2015), the Court found that Plaintiff's state law, Maryland, failure to warn claim was parallel to the federal requirements and thus was not preempted. The Court found that "this [failure to warn] claim is parallel to several federal duties imposed by the PMA, for example the duty to provide the FDA with "Adverse Reaction" reports. *Id.* at 742. *Plaintiff's Memorandum in Opposition to Defendant's Motion for Summary Judgment*, p. 14.

Similarly, the Fourth Circuit recognizes that North Carolina's failure to warn claims pursuant to N.C. Gen. Stat. Ann. § 99B-5(a) are not preempted. *See generally, Carlson v. Boston Sci. Corp.*, 856 F.3d 320 (4th Cir. 2017). A plaintiff may prevail on this failure-to-warn claim if the defendant unreasonably failed to provide an adequate warning, such failure was the proximate cause of the plaintiff's damages, and the product "posed a substantial risk of harm" without an adequate warning *either at the time of or after leaving the manufacturer's control*. *Carlson v. Boston Sci. Corp.*, 856 F.3d 320, 324 (4th Cir. 2017) (emphasis added).

IV. Conclusion

Here, a fact-specific inquiry is required in order to determine if the manufacturer defendant breached a state duty parallel to the federal duty. Dismissal as a matter of law is not warranted and Plaintiff would be severely prejudiced if she were not given the opportunity to conduct discovery for this issue. Plaintiff respectfully requests that this Court not grant Defendant's motion for summary judgement and allow Plaintiff to conduct a fact-intensive inquiry into whether the Manufacturers breached their state and federal duty to warn and warranty.

Respectfully Submitted,

Dated: New York, New York
April 8, 2019

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CERTIFICATE OF SERVICE

I hereby certify that on April 8, 2019, I caused the foregoing supplemental brief to be filed with the United States District Court or the Eastern District of North Carolina Western Division via the Court's CM/ECF system.

Dated: April 8, 2019

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